

REMARKS

Claims 1 and 31-75 are in the application.

No claims are amended herein.

Entry of this Reply, reexamination and reconsideration of the application are respectfully requested in light of the Declaration under 37 CFR 1.132 of Gerald E. McDonnell submitted herewith and the following remarks.

Declaration Under 37 CFR 1.132 of Gerald E. McDonnell

Applicants submit herewith the Declaration under 37 CFR 1.132 of Gerald E. McDonnell, one of the inventors of the present application. This Declaration includes a brief discussion of the need for a prion surrogate for use in testing prion decontamination compositions and processes, and includes data showing that IFDO is an effective and valid surrogate for prions in such testing. Applicants respectfully submit that this Declaration fully responds to the Examiner's concerns and overcomes any possible contention that the present application lacks an enabling disclosure with respect to effectiveness of the claimed process against prions.

Rejection Under 35 USC §112, First Paragraph

Claims 1 and 31-75 stand rejected as lacking enabling disclosure. Applicants respectfully traverse this rejection for at least the following reasons.

Applicants incorporate by reference all of the previous arguments and information submitted in support of the foregoing traverse of this rejection.

Applicants submit herewith the Declaration under 37 CFR 1.132 of Gerald E. McDonnell, which unequivocally demonstrates that the presently disclosed and claimed invention is fully enabled. Specifically, the Declaration submits evidence showing that the use of IFDO is fully predictive of both success and failure of a wide range of prion decontamination compositions and processes.

Applicants respectfully submit that, in light of the presently submitted Declaration, and further in view of the previously submitted evidence, that Applicants' disclosure fully enables the skilled person to make and use the claimed invention. Based on the foregoing, Applicants respectfully submit that the presently claimed invention is fully

enabled to the person of skill in the art in accordance with 35 U.S.C. 112, 1st paragraph.

For all of the foregoing reasons, Applicants respectfully submit that the presently claimed invention is, and was at the time the present application was filed, fully enabled in accordance with 35 USC §112, 1st paragraph, and accordingly Applicants respectfully request withdrawal of this ground of rejection.

Rejections Under 35 USC §103(a)

Claims 1, 31-40, 45-52 and 55-74 stand rejected under 35 U.S.C. §103(a) as unpatentable over Prusiner (US 6720355) and Ernst and Race (Ernst et al., "Comparative analysis of scrapie agent inactivation methods," *Journal of Virological Methods*, 41 (1993) 193-202). Claims 54 and 75 stand rejected as obvious over Prusiner and Ernst and Race, and further in view of Foster, (US 7252720). Claim 53 stands rejected as obvious over Prusiner and Ernst and Race, and further in view of McDonnell (US 7001873) and/or Narayanan (US 5326789).

Applicants respectfully traverse each of the foregoing rejections for at least the following reasons, as well as for the reasons set forth in the previous Reply to Office Action, which are incorporated herein by reference.

In response to Applicants' previous arguments, the Examiner again contended that these results are somehow undermined or are less legitimate since IFDO was used as the target or test material, as opposed to actual prions. Appellants respectfully submit that for the reasons set forth above, IFDO is in fact a suitable model for investigating agents for use against prions, and that persons of skill in the art already know and accept this. Given that Applicants have shown quite unexpected results in the Examples using IFDO, and given that the foregoing patents and the two Burden publications fully support use of this model, Applicants again submit that the unexpectedly good results reported in the Examples fully rebut any possible *prima facie* case of obviousness.

To the extent that the obviousness rejections are based on the alleged lack of enablement, this alleged basis has been fully addressed and rendered moot by the foregoing.

Applicants respectfully submit that the obviousness rejections lack basis and should be withdrawn, since no *prima facie* case of obviousness has been stated.

Even if the Office Actions have set forth a *prima facie* case of obviousness, Applicants' examples show a synergistic effect that overcomes any such *prima facie* case. In each instance, superior results are obtained when the formulations within the scope of the Applicants' claims 1 and 56 are used, as compared to similar formulations outside the scope of the present claims.

Thus, even if it might have been *prima facie* obvious to combine the sulfonate of Prusiner with a composition such as the LpH formulation, Applicants' examples show that an unexpected synergy is exhibited by the claimed combination, which could not have been expected based on the disclosures of the prior art.

For the foregoing reasons, Applicants respectfully submit that the presently claimed invention of claims 1 and 56, and the claims dependent thereon, would not have been obvious over Prusiner in view of Ernst and Race.

Claim 45 would not have been obvious for an additional reason: the Office Action fails to state a legally correct *prima facie* case of obviousness, since the rejection is supported by nothing more than speculation about what might have happened.

Claim 45 recites that at least one of the phenols in the combination of phenols has a Log P_c value of at least about 2.5. As noted in the specification at page 13, lines 29-37, Applicants found that the solubility of the phenol in the composition has an effect on the degree to which the protein is complexed, and that, in general, the lower the solubility of the phenol in the formulation, the greater the degree of complexation, i.e., the more effective the phenol formulation is at prion inactivation. Example 3 correlates the partition coefficients, expressed as log P_c , with the results in log IFDO reduction.

Despite its lack of citation to any authority, the Office Action, at page 9, contends that it would have been obvious to combine the teachings of Prusiner and Ernst and Race to include at least one phenol with a Log P_c value of at least about 2.5. As Applicants noted in the previously Reply to Office Action, this contention is completely unsupported by any citation to any authority or disclosure. There is simply no evidence that would have even suggested such a factor could possibly be important in selecting

at least one phenol for inclusion in a composition for use in a method of inactivating prions. Accordingly, there is no basis for this rejection and it should be withdrawn.

Applicants' argument relating to the use of water in Prusiner and Ernst and Race simply notes that, since these references teach aqueous media, that such teaching would, if anything, lead one away from the use of a phenol having a greater hydrophobicity, which is what Log P_c measures. Since the prior art uses an aqueous system, absent any teaching to the contrary, a person of ordinary skill would expect agents having greater hydrophilic nature, i.e., greater solubility in the aqueous system, not greater hydrophobic nature, i.e., less solubility in the aqueous system, to have been more effective. This point is quite clear, and Applicants fail to see any basis for the Examiner's contention that is not clear. The evidence in support of Applicants' arguments is in Applicants' examples. In contrast, the Examiner has cited no evidence whatsoever to support the contention that it would have been obvious to do what is claimed in claim 45. Accordingly, Applicants respectfully submit that there is no factual support for this rejection.

Accordingly, for this reason, in addition to the reasons above for the base claim, Applicants respectfully submit that the invention described in claim 45 would not have been obvious over the contended combination of Prusiner and Ernst and Race.

Applicants respectfully submit that claim 1 would not have been obvious over the prior art cited by the Examiner. Claims 31-55 depend from amended claim 1 and would not have been obvious over the cited references for at least the same reasons that claim 1 would not have been over such references. Withdrawal of the rejection is believed to be warranted and is respectfully requested.

Applicants respectfully submit that claim 56 would not have been obvious over the prior art cited by the Examiner. Claims 57-75 depend from claim 56 and also would not have been obvious over the cited references for the same reasons. Withdrawal of the rejection is believed to be warranted and is respectfully requested.

Telephone Interview Summary

On 05 January 2011, Applicants' undersigned attorney and the Examiner conducted a telephonic interview, to discuss the outstanding issues in this application. The interview included discussion of possible claim amendments and discussed a

possible declaration to submit data showing the IFDO is an effective surrogate for prions. The present Reply to Office Action, including the Declaration of Gerald E. McDonnell is a direct result of the discussion in this regard in the interview. As indicated in the Examiner's Interview Summary mailed 14 January 2011, agreement was not reached regarding the claims.

The present interview summary constitutes Applicants' submission summarizing the substance of the interview, as required by MPEP 713.04.

Conclusion

Applicants respectfully submit that the application is in condition for allowance. A Notice of Allowance is respectfully requested.

Any additional fees required for the filing of this paper may be charged to Deposit Account No. 18-0988. In the event the Examiner would like to discuss any matter involving this application with the Applicants, he is invited to contact the undersigned attorney by telephone.

Respectfully submitted,

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